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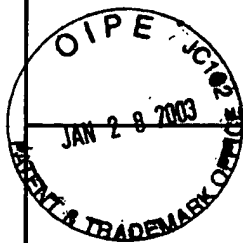
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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))Docket No. 464
UAB-20702/22S
#3

In Re Application Of: Steven E. Ealick et al.

Serial No.
10/035,300Filing Date
October 26, 2001

Examiner

Group Art Unit
1645Title: **MUTANT PURINE NUCLEOSIDE PHOSPHORYLASE PROTEINS AND CELLULAR DELIVERY THEREOF**

Address to:

Assistant Commissioner for Patents
Washington, D.C. 20231**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).**RECEIVED**
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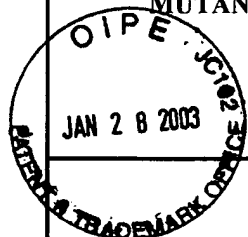
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Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

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Avery N. Goldstein, Reg. No. 39,204

Attorney for Applicant

Gifford, Krass, Groh, Sprinkle,

Anderson & Citkowski, P.C.

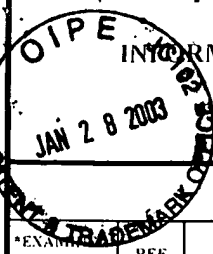
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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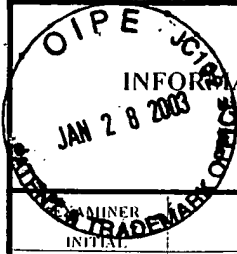
OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	ANDERSON (2001) Editorial Excitement in Gene Therapy!
	Human Gene Therapy, Volume 12, pp. 1483-1484
/	ANDREANSKY et al. (1996) The application of genetically engineered herpes simplex viruses to the treatment of experimental brain tumors
	Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 11313-11318

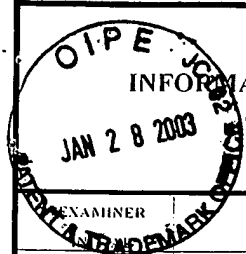
EXAMINER

DATE CONSIDERED

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 <p align="center">INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)</p>		Docket Number (Optional) UAB-20702/22	Application Number 10/035,300
		Applicant(s) S. Ealick et al.	
		Filing Date October 26, 2001	Group Art Unit 1645
OTHER DOCUMENTS (Including: Author, Title, Date, Pertinent Pages, Etc.)			
EXAMINER INITIAL	/	BECK et al. (1995) The Thymidine Kinase/Ganciclovir-Mediated "Suicide" Effect is Variable in Different Tumor Cells Human Gene Therapy, Volume 6, pp. 1525-1530	
	/	BISCHOFF et al. (1996) An Adenovirus Mutant That Replicates Selectively in p53-Deficient Human Tumor Cells Science, Vol. 274, pp. 373-376	
	/	CACCIAPUOTI et al. (1994) Purification and Characterization of Extremely Thermophilic and Thermostable 5'-Methylthioadenosine Phosphorylase from the Archaeon <i>Sulfolobus solfataricus</i> The Journal of Biological Chemistry, Volume 269, No. 40, pp. 24762-24769	
	/	CACCIAPUOTI et al. (1996) Extremely thermophilic and thermostable 5'-methylthioadenosine phosphory from the archaeon <i>Sulfolobus solfataricus</i> Gene Cloning and amino acid sequence determination Eur. J. Biochem., Volume 239, pp. 632-637	
	/	DILBER et al. (1997) Gap Junctions Promote the Bystander Effect of Herpes Simplex Virus Thymidine Kinase <i>in Vivo</i> Cancer Research, No. 57, pp. 1523-1528	
	/	DIX et al. (2001) Minireview: Does the Antitumor Adenovirus ONYX-015/d11520 Selectively Target Cells Defect in the p53 Pathway? Journal of Virology, pp. 5443-5447	
	/	DORONIN et al. (2001) Tissue-Specific, Tumor-Selective, Replication-Competent Adenovirus Vector for Cancer Gene Therapy Journal of Virology, pp. 3314-3324	
	/	ELSHAMI et al. (1996) Gap junctions play a role in the 'bystander effect' of the herpes simplex virus thymidine kinase/ganciclovir system in vitro Gene Therapy 3, pp. 85-92	
	/	FREEMAN et al. (1993) The "Bystander Effect": Tumor Regression When a Fraction of the Tumor Mass is Genetically Modified Cancer Research 53, pp. 5274-5283	
	/	GE et al. (1997) Transduction of Cytosine Deaminase Gene Makes Rat Glioma Cells Highly Sensitive to 5-Fluorocytosine Int. J. Cancer, No. 71, pp. 675-679	
	/	GNANT et al. (1999) Systemic Administration of a Recombinant Vaccinia Virus Expressing the Cytosine Deaminase Gene and Subsequent Treatment with 5-Fluorocytosine Leads to Tumor-specific Gene Expression and Prolongation of Survival in Mice Cancer Research 59, pp. 3396-3403	
	/	HALL et al. (1998) p53-dependent cell death/apoptosis is required for a productive adenovirus infection Nature Medicine, Volume 4, No. 9, pp. 1068-1072	
EXAMINER		DATE CONSIDERED	

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S. Ealick et al.

Filing Date

October 26, 2001

Group Art Unit

1645

OTHER DOCUMENTS (Including: Author, Title, Date, Pertinent Pages, Etc.)

HEISE et al. (1997) ONYX-015, an E1B gene-attenuated adenovirus, causes tumor-specific cytolysis and antitumoral efficacy that can be augmented by standard chemotherapeutic agents

Nature Medicine, Volume 3, Number 6, pp. 639-645

HEISE et al. (1999) Intravenous Administration of ONYX-015, a Selectively Replicating Adenovirus, Induces Antitumoral Efficacy

Cancer Research 59, pp. 2623-2628

HUANG et al. (1987) Phosphorolytic Cleavage of 2-Fluoroadenine from 9-B-D-Arabinofuranosyl-2-Fluoroadenine by *Escherichia Coli* A Pathway for 2-Fluoro-Atp Production

Biochemical Pharmacology, Vol. 30, No. 18, pp. 2945-2950

HUBER et al. (1994) Metabolism of 5-fluorouracil in human colorectal tumor cells transduced with the cytosine deaminase gene: Significant antitumor effects when only a small percentage of tumor cells express cytosine deaminase

Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 8302-8306

IMAIZUMI et al. (1998) Bystander Tumoricidal Effect and Gap Junctional Communication in Lung Cancer Cell Lines

American Journal of Respiratory Cell and Molecular Biology, Volume 18, No. 2, pp. 205-212

JAFFE (1975) Nucleoside Analogs as Antiparasitic Agents

Annals of the New York Academy of Sciences, Chemistry, Biology, and Clinical Uses of Nucleoside Analogs, Vol. 255, pp. 306-316

JOHNSON et al. (2002) Selectively replicating adenoviruses targeting deregulated E2F activity are potent, systemic antitumor agents

Cancer Cell, Vol. 1, pp. 325-337

KHURI et al. (2000) A controlled trial of intratumoral ONYXA-015, a selectively-replicating adenovirus, in combination with cisplatin and 5-fluorouracil in patients with recurrent head and neck cancer

Nature Medicine, Volume 6, No. 8, pp. 879-885

LANE (1998) Killing tumor cells with viruses-a question of specificity

Nature Medicine, Volume 4, No. 9, pp. 1012-1013

LEMMON et al. (1997) Anaerobic bacteria as a gene delivery system that is controlled by the tumor microenvironment

Gene Therapy 4, pp. 791-796

LINKE (1998) Has the smart bomb been diffused?

Nature, Volume 395, pp. 13 and 15

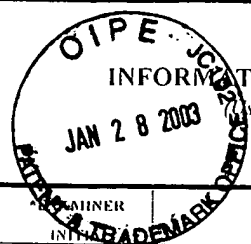
LOWE (1997) Progress of the smart bomb cancer virus. A mutant adenovirus capable of preferentially destroying cancer cells shows promise in preclinical studies (639-645).

Nature Medicine, Volume 3, No. 6, pp. 606-607

EXAMINER

DATE CONSIDERED

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Group Art Unit

1645

OWNER
INITIALS

OTHER DOCUMENTS (Including: Author, Title, Date, Pertinent Pages, Etc.)

✓ MA et al. (2002) Cells Designed to Deliver Anticancer Drugs by Apoptosis

Cancer Research 62, pp. 1382-1387

✓ NEMUNAITIS et al. (2001) Phase II Trial of Intratumoral Administration of ONY-015, a Replication-Selective Adenovirus, in Patients With Refractory Head and Neck Cancer

Journal of Clinical Oncology, Vol. 19, No. 2, pp. 289-298

✓ NEMUNAITIS et al. (2001) Intravenous infusion of a replication-selective adenovirus (ONYX-015) in cancer patients: safety, feasibility and biological activity.

Gene Therapy, Abstract, 2 pages

✓ PENNISI (1998) Training Viruses to Attack Cancers

COFFEY et al. (1998) Reovirus Therapy of Tumors with Activated Ras Pathway

Science, Vol. 282, pp. 1244-1246 and 1332-1334

✓ RAM et al. (1993) *In Situ* Retroviral-mediated Gene Transfer for the Treatment of Brain Tumors in Rats

Cancer Research 53, pp. 83-88

✓ ROTHMANN et al. (1998) Replication of ONYX-015, a Potential Anticancer Adenovirus, is Independent of p53 Status in Tumor Cells

Journal of Virology, Vol. 72, pp. 9470-9478

✓ SACCO et al. (1996) Partial regression yet incomplete eradication of mammary tumors in transgenic mice by retrovirally mediated HSVtk transfer 'in vivo'

Gene Therapy 3, pp. 1151-1156

✓ SEARLE et al. (1998) Adenoviral vectors: not to be sneezed at

Gene Therapy 5, pp. 725-727

(SHANGHUA et al. (no date) Cloning and Expression of the Enterobacter aerogenes W8401 Purine Nucleoside Phosphorylase Gene in Escherichia coli

Genetic Engineering Opening Lab, Fudan University, Shanghai, 5 pages

✓ SHANGHUA et al. (no date) The Nucleotide Sequence of Purine Nucleoside phosphorylase Gene from Enterobacter aerogenes W8401

4 pages

(SHINOURA et al. (1999) Highly Augmented Cytopathic Effect of a Fiber-mutant E1B-defective Adenovirus for Gene Therapy of Gliomas

Cancer Research 59, pp. 3411-3416

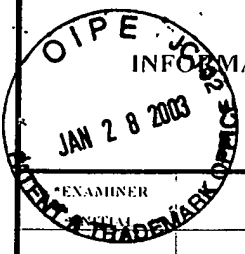
(WILDNER et al. (1999) Therapy of Colon Cancer with Oncolytic Adenovirus is Enhanced by the Addition of Herpes Simplex Virus-thymidine kinase

Cancer Research 59, pp. 410-413

EXAMINER

DATE CONSIDERED

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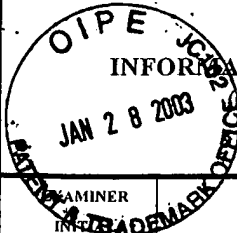
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OTHER DOCUMENTS (Including: Author, Title, Date, Pertinent Pages, Etc.)

YEH et al. (1997) Advances in adenoviral vectors: from genetic engineering to their biology
The FASEB Journal, Vol. 11, pp. 615-623

EXAMINER	DATE CONSIDERED
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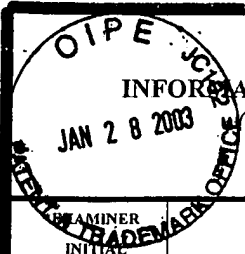
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
✓	ALLEN (1989) Stealth™ Liposomes: Avoiding Reticuloendothelial Uptake Liposomes in the Therapy of Infectious Diseases and Cancer, pp. 405-415.	
/	BARANKIEWICZ and JEZEWSKA (1975) Inosine-Guanosine and Adenosine Phosphorylase Activities in Hepatopancreas of <i>Helix pomatia</i> (Gastropoda) Comp. Biochem. Physiol., Vol. 54B, pp. 239-242.	
✓	BENNETT et al. (1984) Mode of Action of 2-amino-6-chloro-1-deazapurine Biochemical Pharmacology, Vol. 33, No. 2, pp. 261-271.	
	BOHMAN et al. (1983) Mechanism of Cytostatic Action of Novel 5-(Thien-2-yl) and 5-(Furan-2-yl)-Substituted Pyrimidine Nucleoside Analogues Against Tumor Cells Transfected by the Thymidine Kinase Gene of Herpes Simplex Virus The Journal of Biological Chemistry, Vol. 269, No. 11, pp. 8036-8043.	
✓	BROCKMAN et al. (1980) Metabolism and Chemotherapeutic Activity of 9-β-D-Arabinofuranosyl-2-fluoroadenine against Murine Leukemia L1210 and Evidence for Its Phosphorylation by Deoxycytidine Kinase Cancer Research, 40:3610-3615.	
✓	BURLAND et al. (1995) Analysis of the <i>Escherichia coli</i> Genome VI: DNA Sequence of the Region From 92.8 Through 100 Minutes Nucleic Acids Research, Vol. 23, No. 12, pp. 2105-2119.	
✓	CARSON et al. (1980) Deoxycytidine Kinase-Mediated Toxicity of Deoxyadenosine Analogs Toward Malignant Human Lymphoblasts <i>in vitro</i> and Toward Murine L1210 Leukemia <i>in vivo</i> Proc. Natl. Acad. Sci. USA, Vol. 77, No. 11, pp. 6865-6869.	
✓	CONNORS (1995) The Choice of Prodrugs for Gene Directed Enzyme Prodrug Therapy of Cancer Gene Therapy, 2:702-709.	
✓	COOK et al. (1985) Crystallization and Preliminary X-ray Investigation of Purine-nucleoside Phosphorylase from <i>Escherichia coli</i> The Journal of Biological Chemistry, Vol. 260, No. 24, Issue of October 25, pp. 12968-12969.	
✓	CULVER and BLEASE (1994) Gene Therapy for Cancer Trends in Genetics, 10:174-178.	
/	DA COSTA et al. (1996) Converting Cancer Genes into Killer Genes Proc. Natl. Acad. Sci. USA, 93:4192-4196.	
/	DADDONA et al. (1986) Expression of Human Malaria Parasite Purine Nucleoside Phosphorylase in Host Enzyme-deficient Erythrocyte Culture The Journal of Biological Chemistry, Vol. 261, Issue of September 5, pp. 11667-11673.	

EXAMINER	DATE CONSIDERED
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Group Art Unit

1645

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/ DEWEY and KIDDER (1973) Partial Purification and Properties of a Nucleoside Hydrolase from *Crithidia*
Archives of Biochemistry and Biophysics, 157:380-387.

/ DYKES et al. (1992) Development of Human Tumor Xenograft Models for *in vivo* Evaluation of New Antitumor Drugs
Contri. Oncol. Basel, Karger, 42:1-22.

/ EALICK et al. (1990) Three-dimensional Structure of Human Erythrocytic Purine Nucleoside Phosphorylase at 3.2 Å Resolution

The Journal of Biological Chemistry, Vol. 265, No. 3, Issue of January 25, pp. 1812-1820.

/ FREEMAN et al. (1996) *In situ* Use of Suicide Genes for Cancer Therapy

Seminars in Oncology, 23:31-45.

/ FREIREICH et al. (1966) Quantitative Comparison of Toxicity of Anticancer Agents in Mouse, Rat, Hamster, Dog, Monkey and Man

Cancer Chemotherapy Reports, Vol. 50, No. 4, pp. 219-244.

/ GADI et al. (2000) *In vivo* Sensitization of Ovarian Tumors to Chemotherapy by Expression of *E.coli* Purine Nucleoside Phosphorylase in a Small Fraction of Cells

Gene Therapy, 7:1738-1743.

/ GARVER et al. (1994) Strategy for Achieving Selective Killing of Carcinomas

Gene Therapy I, 46-50.

/ GAY (1984) Construction and Characterization of an *Escherichia coli* Strain with a *uncI* Mutation

J. Bacteriol, 158:820-825.

/ GHODA et al. (1988) Substrate Specificities of 5'-deoxy-5'-methylthioadenosine Phosphorylase from *Trypanosoma brucei brucei* and Mammalian Cells

Molecular and Biochemical Parasitology, 27:109-118.

/ GIEBEL et al. (1991) Organization and Nucleotide Sequences of the Human Tyrosinase Gene and a Truncated Tyrosinase-Related Segment
Genomics, 9:435-445.

/ GUTTERIDGE and DAVIES (1981) Enzymes of Purine Salvage in *Trypanosoma cruzi*

FEBS Letters, Vol. 127, No. 2, pp. 21-24.

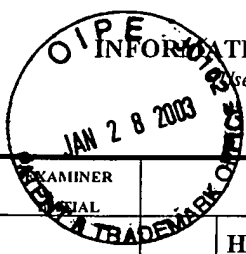
/ HATANKA et al. (1975) Adenine Formation from Adenosine by Mycoplasmas: Adenosine Phosphorylase Activity.

Proc. Natl. Acad. Sci. USA, 77:1401-1405.

EXAMINER

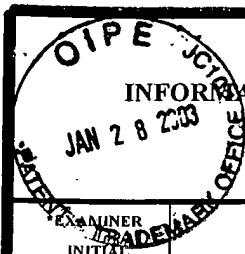
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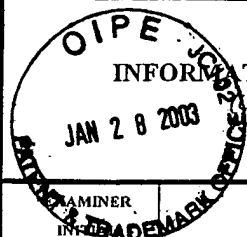
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EXAMINER	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
/	HERSHFIELD et al. (1991) Use of Site-Directed Mutagenesis to Enhance the Epitope-Shielding Effect of Covalent Modification of Proteins with Polyethylene Glycol Proc. Natl. Acad. Sci. USA, 88:7185-7189.		
/	HEYWORTH et al. (1982) Purine Metabolism in <i>Trichomonas vaginalis</i> FEBS Letters, Vol. 1, No. 1, pp. 106-110.		
/	HUGHES et al. (1995) Bystander Killing of Melanoma Cells Using the Human Tyrosinase Promoter to Express the <i>Escherichia coli</i> Purine Nucleoside Phosphorylase Gene Cancer Research, 55:3339-3345.		
/	HUGHES et al. (1998) Cell to Cell Contact is not Required for Bystander Cell Killing by <i>Escherichia coli</i> Purine Nucleoside Phosphorylase The Journal of Biological Chemistry, Vol. 273, No. 4, Issue of January 23, pp. 2322-2328.		
/	JENSEN (1978) Two Purine Nucleoside Phosphorylases in <i>Bacillus subtilis</i> . Purification and Some Properties of the Adenosine-Specific Phosphorylase Biochimica et Biophysica Acta, 525:346-356.		
/	JENSEN and NYGAARD (1975) Purine Nucleoside Phosphorylase from <i>Escherichia coli</i> and <i>Salmonella typhimurium</i> Eur. J. Biochem., 51:253-265.		
/	JENUTH and SNYDER (1991) Nucleotide Sequence of Murine Purine Nucleoside Phosphorylase cDNA Nucleic Acids Research, Vol. 19, No. 7, pp. 1708.		
/	JIAO et al. (1993) Long-Term Correction of Rat Model of Parkinson's Disease by Gene Therapy Nature, 362:450-453.		
<	KIDDER et al. (1979) The Purine Phosphoribosyltransferases of <i>Crithidia fasciculata</i> J. Parasitol., 64(4), pp. 520-525.		
/	KIKUCHI et al. (1989) Characteristic Sequences in the Upstream Region of the Human Tyrosinase Gene Biochimica et Biophysica Acta., 1009:283-286.		
/	KOELLNER et al. (1998) Crystal Structure of the Ternary Complex of <i>E.coli</i> Purine Nucleoside Phosphorylase with Formycin B, a Structural Analogue of the Substrate Inosine, and Phosphate (Sulphate) at 2.1 Å Resolution Journal of Molecular Biology, pp. 153-166.		
/	KOLLS et al. (1994) Prolonged and Effective Blockade of Tumor Necrosis Factor Activity Through Adenovirus-mediated Gene Transfer Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 215-219.		
EXAMINER		DATE CONSIDERED	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
EXAMINER INITIAL	✓	KÖNIGK (1978) Purine Nucleotide Metabolism in Promastigotes of <i>Leishmania tropica</i> : Inhibitory Effect of Allopurinol and Analogues of Purine Nucleosides. Tropmed. Parasit., 29:435-438.	
	✓	KOSZALKA and KRENITSKY (1978) Nucleosidases from <i>Leishmania donovani</i> The Journal of Biological Chemistry, Vol. 254, No. 17, Issue of September 10, pp. 8185-8193.	
	✓	KROHNE et al. (2001) Mechanisms of Cell Death Induced by Suicide Genes Encoding Purine Nucleoside Phosphorylase and Thymidine Kinase in Human Hepatocellular Carcinoma Cells <i>in vitro</i> Hepatology, Vol. 34, No. 3, pp. 511-518.	
	✓	LOCKETT et al. (1997) Relative Efficiency of Tumor Cell Killing <i>in vitro</i> by Two Enzyme-prodrug Systems Delivered by Identical Adenovirus Vectors Clinical Caner Research, Vol. 3, pp. 2075-2080.	
	✓	MAO et al. (1997) The Crystal Structure of <i>Escherichia coli</i> Purine Nucleoside Phosphorylase: A Comparison with the Human Enzyme Reveals a Conserved Topology Structure, Vol. 5, No. 10, pp. 1373-1383.	
	✓	MARTINELLO-WILKS et al. (1998) <i>In vivo</i> Gene Therapy for Prostate Cancer: Preclinical Evaluation of Two Different Enzyme-directed Prodrug Therapy Systems Delivered by Identical Adenovirus Vectors Human Gene Therapy, 9:1617-1626.	
	✓	MAYNES et al. (1999) Design of an Adenosine Phosphorylase by Active-site Modification of Murine Purine Nucleoside Phosphorylase Biochem. J., 344, pp. 585-592.	
	✓	MAYNES et al. (2000) Further Refinement on the Engineering of Adenosine Phosphorylase from Purine Nucleoside Phosphorylase Purine and Pyrimidine Metabolism in Man X, 21, pp. 107-110.	
	✓	McELWAIN et al. (1988) <i>Acholeplasma laidlawii</i> B-PG9 Adenine-specific Purine Nucleoside Phosphorylase that Accepts Ribose-1-Phosphate, Deoxyribose-1-Phosphate, and Xylose-1-Phosphate Journal of Bacteriology, 170:564-567.	
	✓	MELTON et al. (1999) The Use of Prodrugs in Targeted Anticancer Therapies S.T.P. Pharma Sciences, 9(1), pp. 13-33.	
	✓	MIECH et al. (1975) Pathways of Nucleotide Metabolism in <i>Schistosoma Mansoni</i> -VI-Adenosine Phosphorylase Biochemical Pharmacology, 24:407-411.	
	✓	MILLER and ROSMAN (1989) Improved Retroviral Vectors for Gene Transfer and Expression BioTechniques, 7:980-991.	
EXAMINER		DATE CONSIDERED	

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



INFORMATION DISCLOSURE CITATION

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Docket Number (Optional)

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Filing Date

October 26, 2001

Group Art Unit

1645

EXAMINER
IN-108

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓ MOHR et al. (2000) Gene Therapy of Hepatocellular Carcinoma *in vitro* and *in vivo* in Nude Mice by Adenoviral Transfer of the *Escherichia coli* Purine Nucleoside Phosphorylase Gene
Hepatology, Vol. 31, No. 3, pp. 606-614.

✓ MONTGOMERY and HEWSON (1968) Analogs of 6-Methyl-9-β-D-ribofuranosylpurine
J. Med. Chem., 11:48-52.

✓ MOOLTEN (1994) Drug Sensitivity ("Suicide") Genes for Selective Cancer Chemotherapy
Cancer Gene Therapy, 1:279-287.

✓ MULLEN (1994) Metabolic Suicide Genes in Gene Therapy
Pharmac. Ther., 63:199-207.

✓ NELSON et al. (1992) Isolation and Expression of a Murine Purine Nucleoside Phosphorylase-encoding cDNA and Sequence Similarity with the Human Message
Gene, 113:215-221

✓ NESTLER et al. (1997) Foamy Virus Vectors for Suicide Gene Therapy
Gene Therapy, 4:1270-1277.

✓ NICULESCU-DUVAZ et al. (1998) Gene-directed Enzyme Prodrug Therapy
Bioconjugate Chem., 9:4-22.

✓ PARK et al. (1997) Upregulation of Tissue-Specific Suicide Gene Expression in Melanoma Using a Melanocyte-Specific Enhancer Results in Increased Cytotoxicity of the Purine Nucleoside Phosphorylase Gene in Melanoma
Human Gene Therapy, 10:889-898.

✓ PARK et al. (1999) Augmentation of Melanoma-Specific Gene Expression Using a Tandem Melanocyte-Specific Enhancer Results in Increased Cytotoxicity of the Purine Nucleoside Phosphorylase Gene in Melanoma
Human Gene Therapy, 10:889-898.

✓ PARKER et al. (1997) *In vivo* Gene Therapy of Cancer with *E.coli* Purine Nucleoside Phosphorylase
Human Gene Therapy 8:1637-1644.

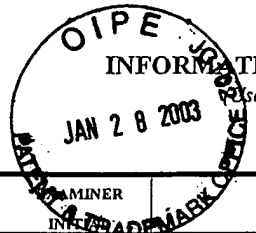
✓ PARKER et al. (1998) Metabolism and Metabolic Actions of 6-Methylpurine and 2-Fluoroadenine in Human Cells
Biochemical Pharmacology, Vol. 55, pp. 1673-1681.

✓ PUHLMAN et al. (1999) Thymidine Kinase-Deleted Vaccinia Virus Expressing Purine Nucleoside Phosphorylase as a Vector for Tumor-Directed Gene Therapy
Human Gene Therapy, 10:649-657.

EXAMINER

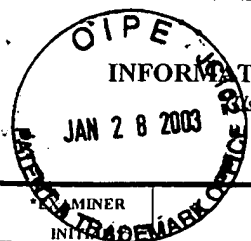
DATE CONSIDERED

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Docket Number (Optional) UAB-20702/22	Application Number 10/035,300
		Applicant(s) S. Ealick et al.	
		Filing Date Oct ber 26, 2001	Group Art Unit 1645
EXAMINER	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	/	REESE (1968) Extracellular Purine β -ribosidases from Fungi Canadian Journal of Microbiology, 14:377-383.	
	(SCHMIDT and KÖNIGK (1975) A Purine Nucleoside Hydrolase from <i>Trypanosoma gambiense</i> , Purification and Properties Tropenmed. Parasit., 26:19-26.	
	/	SECRIST et al. (1999) Gene Therapy of Cancer: Activation of Nucleoside Prodrugs with <i>E.coli</i> Purine Nucleoside Phosphorylase Nucleosides Nucleotides 1999 April/May; 18 (4-5): 745-57.	
	/	SENESI et al. (1976) A Specific Adenosine Phosphorylase, Distinct from Purine Nucleoside Phosphorylase FEBS Letters, Vol. 64, No. 2, pp. 353-357.	
	/	SHIBATA et al. (1992) Identification of a <i>cis</i> -Acting Element that Enhances the Pigment Cell-Specific Expression of the Human Tyrosinase Gene The Journal of Biological Chemistry, Vol. 367, No. 29, pp. 20584-20588.	
	/	SHIRAE and YOKOZEKI (1991) Purifications and Properties of Orotidine-Phosphorylating Enzyme and Purine Nucleoside Phosphorylase from <i>Erwinia carotovora</i> AJ 2992 Agric. Biol. Chem., 55(7), 1849-1857.	
	?	SORSCHER and HUANG (1991) Diagnosis of Genetic Disease by Primer-Specified Restriction Map Modification, with Application to Cystic Fibrosis and <i>Retinitis pigmentosa</i> The Lancet, Vol. 1115-1118.	
	/	SORSCHER et al. (1994) Tumor Cell Bystander Killing in Colonic Carcinoma Utilizing the <i>Escherichia coli</i> DeoD Gene to Generate Toxic Purines Gene Therapy, 1-233-238.	
	/	SPRINGER and NICULESCU-DUVAZ (2000) Prodrug-Activating Systems in Suicide Gene Therapy The Journal of Clinical Investigation, Vol. 105, No. 9, pp. 1161-1167.	
	/	STOECKLER et al. (1997) Purine Nucleoside Phosphorylase. 3. Reversal of Purine Base Specificity by Site-Directed Mutagenesis Biochemistry, Vol. 36, No. 39, pp. 11749-11756.	
	/	STREETER et al. (1980) 7-ribosyl-3-deazaguanine -- Mechanism of Antibacterial Action Biochemical Pharmacology, Vol. 29, pp. 1791-1797.	
	/	TANNOCK (1989) Principles of Cell Proliferation: Cell Kinetics Devita and Hellman, eds. (L.B. Lippincott, Philadelphia), pp. 3-13, reproduced with permission from: Tannock IF, Hill RP: The Basic Science of Oncology Elmsford NY Pergamon Press, 1987.	
EXAMINER	DATE CONSIDERED		

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Applicant(s)

S. Ealick et al.

Filing Date

October 26, 2001

Group Art Unit

1645

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/ TAPSCOTT et al. (1994) Gene Therapy of Rat 9L Gliosarcoma Tumors by Transduction with Selectable Genes Does Not Require Drug Selection
Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 8185-8189.

| TARR (1958) Lingcod Muscle Purine Nucleoside Phosphorylase
Can. J. Biochem. Physiol., 36:517-530.

/ THAM et al. (1993) Identification of *Mycoplasma pirum* Genes Involved in the Salvage Pathways for Nucleosides
Journal of Bacteriology, Vol. 175, No. 16, pp. 5281-5285.

/ TREMBACZ and JEZEWSKA (1993) Specific Adenosine Phosphorylase from Hepatopancreas of Gastropod *Helix pomatia*
Comp. Biochem. Physiol., Vol. 104B, No. 3, pp. 481-487.

2 TRINH et al. (1995) Enzyme/Prodrug Gene Therapy: Comparison of Cytosine Deaminase/5-Fluorocytosine Versus Thymidine Kinase/Ganciclovir Enzyme/Prodrug Systems in a Human Colorectal Carcinoma Cell Line
Cancer Research, 55:4808-4812.

< VAN BERKEL et al. (1991) Receptor-Dependent Targeting of Lipoproteins to Specific Cell Types of the Liver
Targeted Diagnosis and Therapy, 5:225-219.

/ WAGNER et al. (1990) Transferrin-Polycation Conjugates as Carriers for DNA Uptake into Cells
Proc. Natl. Acad. Sci. USA, 87:3410-3414.

/ WHITE et al. (1982) Comparison of the Actions of 9-β-D-Arabinofuranosyl-2-Fluoroadenine and 9-β-D-Arabinofuranosyladenine on Target Enzymes from Mouse Tumor Cells
Cancer Research, 42:2260-2264.

/ WILLIAMS et al. (1984) Human Purine Nucleoside Phosphorylase cDNA Sequence and Genomic Clone Characterization
Nucleic Acids Research, Vol. 12, No. 14, pp. 5779-5787.

/ WU and WU (1988) Receptor-Mediated Gene Delivery and Expression *in vivo*
J. Biol. Chem., 263, 29:14621-14624.

/ XU and McLEOD (2001) Strategies for Enzyme/Prodrug Cancer Therapy
Clinical Cancer Research, Vol. 7, pp. 3314-3324.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

